OMB No. 0990-0115

# Electronic Request for Proposal

## SECTION A – SOLICITATION/CONTRACT FORM

**OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.**

**Purchase Authority: Public Law 92-218, as amended.**
**NOTE: The issuance of this solicitation does not commit the government to an award.**

| **RFP Number:** | **Just In Time:** | **Small Bus. Set-Aside:** [ X ]Yes [ ]No<br>**8(a) Set-Aside:** [ ]Yes [ X]No | **Level of Effort:**<br>[ ] Yes [X ] No |
|---|---|---|---|
| NIH-NIAID-DMID-03-28 | [ ] Yes<br>[ X] No | **NAICS Code:** 541710<br>**Size Standard:** 500 employees | **Total Effort:**<br>[ N/A ] |

**TITLE:**
**Food & Waterborne Diseases Integrated Research Network: Coordinating & Biostatistics Center**

| **Issue Date: July 29, 2002** | **Due Date: November 18, 2002**<br>**Time: 4:00 PM, EST** | **Technical Proposal Page Limits:**<br>[ X ] Yes *(see "How to Prepare and Submit Electronic Proposals")*<br>[ ] No |
|---|---|---|

**ISSUED BY:**

Barbara A. Shadrick
Senior Contracting Officer
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

[ X ] ***We reserve the right to make awards without discussion.***

| **NO. OF AWARDS:** | **PERIOD OF PERFORMANCE:** |
|---|---|
| [X] Only 1 Award<br>[ ] Multiple Awards | 7 years beginning on or about 06/30/2003 |

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

***POINT OF CONTACT*** **-- Lisa Coleman** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

| ***Telephone:*** ***Direct*** **301-496-0612**<br>***Main*** **301-496-0612** | ***Fax*** **301-402-0972** | ***E-Mail***<br>**lc304t@nih.gov** |
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## BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS

### Background

Food & Waterborne Diseases Integrated Research Network:
Coordinating and Biostatistics Center
DMID-03-28

INTRODUCTION

This contract applies to one component of the National Institute of Allergy and Infectious Diseases (NIAID) Food and Waterborne Diseases Integrated Research Network (FWD IRN) multiple procurement that provides support for research programs to develop products to rapidly identify, prevent, treat and diagnose food and waterborne diseases that threaten public health. This solicitation is for the FWD IRN Coordinating and Biostatistics Center (CoBC), an infrastructure to serve as a biostatistical and operations coordinating unit for support of the above research units. The Request for Proposals (RFP) for CoBC and FWD IRN are being released simultaneously. Offerors responding to this RFP should also refer to the RFP for FWD IRN (RFP NIH-NIAID-DMID-03-04) to gain a better understanding of the collaborative efforts for which they will be responsible.

The objective of this contract will be to coordinate elements of study planning and logistics, protocol development and implementation, training and communications, data collection, management and analysis, site monitoring, manuscript preparation, and related clinical trial support activities. This will involve a multicenter effort and a collaborative relationship with clinical investigators, other research investigators, other supporting Contractors, and NIAID staff. Specific responsibilities of the Contractor are described in the Statement of Work.

BACKGROUND

This contract will support the sole NIAID contract activity in food and water-borne diseases. Each year in the United States, the CDC estimates 76 million persons experience foodborne illnesses. Waterborne disease outbreaks associated with drinking water or recreational water occur annually. Vaccines, therapeutics and diagnostics for these infectious diseases are limited. Challenge studies requiring specialized clinical facilities are necessary for some of the vaccine studies. Antibiotic resistance and its relationship to the food supply is an important public health issue without specific focus in NIAID.

In response to the enhanced national emphasis on developing tools for protection against potential agents of bioterrorism, the Enteric Pathogens Research Unit (EPRU) will be expanded to the FWD IRN and include all food and waterborne pathogens and an increase in emphasis on food safety and public health. The EPRU contract was awarded in 1997 for seven years to the University of Maryland (Principal Investigator Dr. Carol Tacket), with sub-contracts at Baylor College of Medicine (Norwalk VLP vaccines, Norwalk challenge model development) and University of Alabama (mutant toxin adjuvants, polio replicon vaccines, toxin transit to brain following intranasal administration). In order to meet critical emerging needs after award of the contract, additional sub-contracts were established with Michigan State University (STEC Reference Center and Strain repository), University of Kansas (establishment of a dog infection model for E. coli O157:H7), University of Colorado (ribotyping of bacterial flora obtained from Crohn's disease patients and controls), Mt. Sinai Hospital (collection and analysis of surgically resected tissue from Crohn's patients and controls), University of Central Florida (culturing of Mycobacterium paratuberculosis from Crohn's tissue specimens), and the Uniformed Services University of the Health Sciences (monkey model for polio-replicon-based vaccines for H. pylori). The establishment of a network of investigators capable of bringing a breadth of expertise to contract activities is an important characteristic of the EPRU. Examples of clinical research conducted under the EPRU include studies of edible vaccines, the use of mutant V. cholerae and E. coli toxin adjuvants delivered orally or by transcutaneous vaccination, and the development of Norwalk Virus challenge pools. Human research studies include development of methods to measure antibody production in mucosal tissue explants in culture, and the search for a possible microbial etiology of Crohn's disease in bowel tissue.

This solicitation is for the Biostatistics and Coordinating Center (CoBC) which will support the FWD IRN. The FWD IRN (RFP NIH-NIAID-DMID-03-04) will include a consortium of multiple units which together will be capable of multi-disciplinary research. The NIAID research agenda in Food and Waterborne Diseases will be implemented at the direction of the Project Officer through the CoBC. The CoBC will coordinate, provide statistics, data management and administrative support for the inter-disciplinary consortia that will address all food and waterborne pathogens (bacteria, viruses and protozoa) to: 1) evaluate vaccines, therapeutics, and rapid detection methods; 2) integrate human mucosal immunity with

clinical research; 3) increase research and product development activities, and 4) include the ecology and microbiology of food- and water-borne zoonoses as well as drug-resistant pathogens. The CoBC will provide the administrative, biostatistical, data management, data analysis, and regulatory support for clinical research. Clinical studies to evaluate vaccine candidates, novel vaccine delivery paradigms and pathogenesis of enteric bacteria with specific mutations have been supported through the EPRU. Summaries of the two ongoing studies (NIAID DMID 00-096 and NIAID DMID 00-001) are available through the NIAID Clinical Trials Database website which can be found at: http://www.niaid.nih.gov/clintrials/ntest.asp.

**Statement of Work**
**Food & Waterborne Diseases Integrated Research Network: Coordinating and Biostatistics Center**
**RFP DMID-03-28**

## INTRODUCTION

The purpose of the contract is to provide support to the Food and Waterborne Diseases (FWD) Integrated Research Network (IRN). The FWD IRN will facilitate the integration of research programs to develop products to rapidly identify, prevent, treat and diagnose food and waterborne diseases that threaten public health. NIAID intends to support 8 (eight) research units and 1 (one) Coordinating and Biostatistics Center (CoBC). The NIAID research agenda in Food and Waterborne Diseases will be implemented at the direction of the Project Officer through the Research Units. The Coordinating and Biostatistics Center will provide the biostatistical and administrative coordination to successfully integrate the research programs in the Network, at the direction of the Project Officer. The FWD IRN will have the following research components: Microbiology Research Unit (2); Immunology Research Unit (2); Zoonoses Research Unit (2); and Clinical Research Unit (2). This inter-disciplinary consortia will addresses all food and waterborne pathogens (bacteria, viruses and protozoa) to: 1) evaluate vaccines, therapeutics, and rapid detection methods; 2) integrate human mucosal immunity with clinical research; 3) increase research and product development activities, and 4) include the ecology and microbiology of food- and water-borne zoonoses as well as drug-resistant pathogens.

Research units are encouraged to develop a broadly based and flexible approach to their area of responsibility. Multidisciplinary research will be achieved through interactive research projects with the other units of the FWD IRN. The research interactions will be facilitated through the FWD IRN Executive Committee and the Coordinating and Biostatistics Center. The Project Officer(s), the Principal Investigator (PI) of each Research Unit, and the PI of the Coordinating and Biostatistics Center will form the FWD IRN Executive Committee. The FWD IRN Executive Committee will participate in review of proposed research projects and make recommendations to the Project Officer as to those that should be conducted in the FWD IRN. Ad Hoc consultants will provide advice to the NIAID regarding research priorities and projects in food and waterborne diseases.

The Coordinating and Biostatistics Center will provide each FWD IRN with statistical support and administrative support (administrative core) for the Research Unit activities and integration with other FWD IRN activities. The FWD IRN investigators will be required to work with the Coordination and Biostatistics Center in the capacities outlined in the below Statement of Work. The Project Officer will effect the NIAID research priorities in food and waterborne diseases through the research activities of the interactive units. Administrative and Biostatistical support will be provided by the Coordinating and Biostatistics Center.

The Coordinating and Biostatistics Center may also be required to interact or support other Division of Microbiology and Infectious Diseases (DMID) studies as directed. In the event of a public health threat, each unit will be required to respond by re-direction of its program. Therefore, it is envisioned that these units will implement, staff and maintain coordinated groups that can provide information needed to enhance the U.S. capacity to better predict, prevent, treat and control food and waterborne diseases especially those included in the NIAID Category A, B, C priority organisms list:
http://www.niaid.nih.gov/dmid/biodefense/bandc_priority.htm

## STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, volunteer populations, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract as needed to conduct the studies as set out below and as approved by the Project Officer.

Specifically, the Contractor shall:

1. The first task of the FWD IRN Executive Committee shall be to prepare a plan for activation of the Food and Waterborne Diseases Integrated Research Network at the direction of the Project Officer in response to a bioterrorist event. This plan must include contact information and a mechanism for rapidly connecting all persons named on the Emergency Response Team. The CoBC shall, at a minimum, coordinate communications of Committee members (meetings, teleconferences, etc.) and prepare and edit documents.

2. Statistical Leadership:

   a. Provide statistical leadership, scientific advice and judgment regarding research options, and clinical trial design expertise for the development and implementation of protocols as assigned. Advice shall address, but not be limited to, alternate design strategies, power, sample size, and impact of interim analyses, and NIH priorities and requirements for inclusion of women and minorities and children, when appropriate, in study populations.

   b. Collaborate with investigators and NIAID staff to develop and refine other aspects of the experimental design of clinical studies, including but not limited to:

      1) delineation of the research questions to be addressed;
      2) consultation on concepts to be developed by the FWD IRN;
      3) selection of appropriate study populations and control or comparison groups;
      4) development of inclusion and exclusion criteria;
      5) definition of clinical endpoints and surrogate markers;
      6) selection of randomization and stratification/blocking methods;
      7) data collection forms/systems;
      8) interim and final analysis methods;
      9) quality assurance methods;
      10) development of recommendations for modifications in the design of ongoing clinical trials with respect to the above parameters, as determined by the Project Officer.

   c. Develop innovative approaches for analyzing outcome data, including development of improved criteria for evaluating disease stages in conjunction with principal investigators, and development of new statistical methods or modification of existing methods for data analysis that will better address relevant clinical research questions.

   d. Provide statistical leadership, scientific advice and judgment regarding research options, and study design expertise for the development and implementation of research studies to be conducted by the Microbiology Research Units, Immunology Research Units, and the Zoonoses Research Units at the direction of the Project Officer.

   e. Collaborate with FWD IRN investigators and NIAID staff to develop and refine other aspects of the experimental design, including but not limited to:

      1) delineation of the research questions to be addressed;
      2) consultation on concepts to be developed by the FWD IRN;
      3) selection of appropriate controls or comparison groups;
      4) selection of randomization of samples and blinding methods;
      5) data collection forms;
      6) interim and final analysis methods.

   f. Attend and participate at meetings and on teleconference calls of the FWD IRN Executive Committee, research committees, and annual meetings.

   g. Provide statisticians for non-FWD IRN DMID Data and Safety Monitoring Boards (DSMB)/ Safety Monitoring Committee (SMC) as this expertise may occasionally be needed elsewhere.

3. Data Management and Systems Development:

   a. Establish and administer state of the art, efficient, reliable, secure and responsive systems for the collection, management, quality assurance and reporting of study data, as well as a system for electronic communication linkages among FWD IRN investigators, the NIAID, the protocol teams, and the FWD IRN Executive Committee.

   b. Develop computer programs and related procedures for the collection, processing, editing, and analysis of all clinical and laboratory study data, including storage, tracking, and retrieval of study data at the central data management facility.

c. For the clinical studies, the CRU takes the lead and works with the CoBC to get the support to produce and distribute standardized forms for collection of all data needed on study subjects, including eligibility, demographic and other baseline data, sequential clinical outcome assessments, serious adverse events and side effects, and laboratory results. Work with the CRU investigators in the development and pre-testing of forms and procedures; reproduce and distribute all forms and revise as directed by the Project Officer. Capacity to develop alternate data entry collection system, i.e., web or fax.

d. For the clinical studies, the CRU takes the lead and works with the CoBC to get the support to provide for centralized computerized registration, randomization, and stratification of all patients on the CRU protocols, or alternative non-computerized methods as directed by the Project Officer, including built-in checks for breakdowns in the assignment process, and procedures for monitoring masking of randomized treatment assignment codes.

e. Collect study data from the study sites. Using the computerized data management system developed in response to item 3.b. above, verify, process, monitor, correct, update, file and store the data securely and in accordance with applicable FDA regulations. Contact study personnel to obtain clarifications or corrections for questionable data or to correct deficiencies.

f. For clinical studies, develop and implement quality assurance and quality control procedures to detect data deficiencies.

g. Evaluate and improve the accuracy, timeliness, and completeness of data submitted by the CRUs at each stage through creation of final datasets, including verification of the clinical and laboratory data used to determine that study participants have reached protocol-defined endpoints.

h. Develop and implement a system for evaluating protocol adherence by the CRUs, and performance and quality of the data from any FWD IRN laboratories.

i. Prepare and provide study data (subject specific and/or summary data) and accompanying documentation to NIAID staff, FWD IRN investigators, other Agencies, or to industrial sponsors, as requested by the Project Officer, to be used for special investigations, selected data analyses, FDA reporting or other purposes. The data shall be provided in a format compatible with the systems and software used by the recipient (NIAID, FWD IRN investigators, and/or other agencies, industrial sponsors) as directed by the Project Officer. Upon completion of each study, prepare a final, cleaned, edited, and documented data set containing all study data. Deliver an electronic copy of the data set to the Project Officer.

j. Provide a state of the art computer system for data management with the potential for expedited processing of selected high-priority information (e.g., randomization assignment, monitoring progress of a particular study, tracking of serious adverse events) and for ready transferal of data and data documentation to NIAID or others at any point during a study. Also, the system shall provide sufficient flexibility and accessibility to answer any inquiries in a timely manner, typically no more than one business day.

k. The security needs to meet NIH requirements. Develop a plan and submit it to DMID for Information Technology Branch (ITB), NIAID approval. Implement and maintain security requirements for the computer system used for data management to:

    1) ensure patient confidentiality for all subject records (both hard copy and electronic).
    2) provide security against anticipated risks, including loss of confidentiality of subject records and viral or catastrophic loss of study data or important software.
    3) Provide security against unauthorized use of data associated with Bioterrorism agents.

l. Establish reliable and secured electronic communication linkages with NIAID and FWD IRN investigators that facilitate sending mail and sharing word processor and data files.

m. Maintain and upgrade software programs that are compatible with changes made in the DMID systems. New software should be developed with the tools recommended by ITB in order to insure integrated operability with the rest of NIAID's databases and infrastructures.

n. Management tools/databases developed in this contract will remain the property of the U.S. Government.

o. At the request of the Project Officer, perform data entry or interact with other NIAID contracts for the exchange of data, movement of samples and investigational products. Contractor may be asked to download or transfer data to other DMID or DMID supported databases.

4. Operations and Support:

a. Provide administrative support to the FWD IRN and the NIAID for the conduct of the FWD IRN clinical trials, including but not limited to:

1) coordination of the activities of FWD IRN investigators, NIAID, appropriate Coordinating and Biostatistics Center staff, and other relevant entities (such as other collaborating agencies and industrial sponsors), and expert committees, for study planning, implementation and analysis, training, and communications, including all necessary logistic and support activities. E-mail and word processing software shall be compatible with that used at NIAID;
2) coordination of the development, preparation, review, and implementation of an overall set of Standard Operating Procedures (SOP) for the interactions of the FWD Research Unit Investigators, incorporating the relevant policies, procedures and requirements of the FWD IRN, NIAID, Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA). The Contractor shall update these SOPs, as directed by the Project Officer, and distribute copies to study sites and NIAID staff.
3) coordinate and provide statistical, technical and administrative support for the activities of the independent Data and Safety Monitoring Boards (DSMB), Safety Monitoring Committees (SMC), and Independent Safety Monitor (ISM). Responsibilities shall include but not be limited to:

a) survey membership of the DSMBs, SMC, ISM and NIAID staff, protocol chairs, industry representatives (if any), for availability in order to schedule meetings and conference calls.
b) prepare a roster of invitees for each protocol review, send letters of invitation, distribute agendas prepared by NIAID as well as relevant protocols, informed consent documents, case report forms, interim analysis reports, or other supporting documents to the DSMB, SMC, ISM, NIAID staff, FWD IRN coordinating unit staff, and other invited participants, as directed by the Project Officer.
c) provide a staff member to handle meeting registration and other logistical matters during the meeting.
d) schedule, arrange and pay for meeting room facilities, including audiovisual equipment; arrange teleconferencing, as necessary.
e) assist non-Federal DSMB, SMC, and ISM with scheduling, reserving transportation and lodging arrangements and provide reimbursement for their transportation, meals and lodging expenses associated with their participation at meetings of their respective groups.
f) prepare and distribute copies of all review summaries to DSMB, SMC, ISM, protocol chairs, the FWD IRN Executive committee, study investigators, Agency representatives (if any), and industry sponsors (if any) if requested by the Project Officer.
g) prepare and distribute at the direction of the Project Officer, minutes of the open meetings and other correspondence.
h) track implementation of action items and submission of DSMB reports by study investigators to their respective Institutional Review Boards (IRBs).

b. Coordinate and provide statistical, technical and administrative support for the activities of the FWD IRN Executive Committee and the Ad Hoc Consultants. Plan and coordinate annual FWD IRN meeting in Bethesda. Responsibilities shall include but not be limited to:

1) survey membership of the FWD IRN Executive Committee, NIAID staff, protocol chairs, FWD IRN investigators (if appropriate) agency representatives (if appropriate), industry representatives (if appropriate), for availability in order to schedule meetings and conference calls;
2) prepare a roster of invitees for each meeting and conference call. Send letters of invitation, distribute agendas prepared by NIAID as well as relevant documents, interim analysis reports, or other supporting documents to the NIAID staff, FWD IRN investigators, Executive Committee membership, and other invited participants, as directed by the Project Officer;
3) provide a staff member to handle meeting registration and other logistical matters during the meeting;
4) schedule, arrange and pay for meeting room facilities, including audiovisual equipment, as necessary;
5) assist non-Federal participants and non-IRN experts or invitees, with scheduling, reserving transportation and lodging arrangements and provide reimbursement for their transportation, meals and lodging expenses associated with their participation at meetings of their respective groups;

6) prepare and distribute copies of all review summaries to the FWD IRN Executive committee, study investigators, Agency representatives (if any), and industry sponsors (if any) if requested by the Project Officer;
7) track implementation of action items and submission.

c. Coordinate with DMID on a standard protocol template consistent with the DMID requirements and a protocol development process in collaboration with NIAID and the CRUs. Use the DMID project/protocol tracking system and forms. With the Project Officer and the Research Unit investigators, define a project review process. Submit to the Project Officer for review and approval within 60 days of award of contract:

d. Develop and maintain a tracking system (including expected completion timelines) in conjunction with the FWD Research Units for development and completion of study projects, protocols, informed consent documents, case report forms, and related documents.

e. Initiate, arrange, and participate in monthly (or more frequently, as needed) conference calls and meetings to develop protocols and address scientific and/or practical issues that may arise during the development and implementation of the studies, and, review progress of the studies. This shall include assembling and distributing necessary materials for these calls and meetings, and preparing minutes and action items as directed by the Project Officer.

f. Track and distribute draft clinical protocols to the appropriate CRU investigators, NIAID staff, Executive committee, and Ad-hoc consultants at the direction of the Project Officer.

g. Oversee the protocol development process in collaboration with the CRU Principal Investigator and coordinator, develop and prepare draft and final protocols and related documents, including informed consent and case report forms, as part of the protocol teams that will include the protocol chair, NIAID representatives, industrial sponsors (if any), and Coordinating and Biostatistics Center representatives consisting of a statistician, clinical trials specialist, and data manager.

h. Provide a repository for current versions of protocols, informed consent documents, and case report forms and other documents (including conference call and meeting minutes) with the capacity to distribute copies to study sites, NIAID staff and others upon request by the Project Officer.

i. Prepare and update, as directed by the Project Officer, a Manual of Operations for each clinical protocol delineating specific instructions, requirements and guidelines for the conduct of clinical trials by the clinical sites, including procedures for the collection, testing, storage and shipping of patient samples, and procedures for data collection, entry, verification and storage.

j. Design, produce, and distribute labels for study materials, test articles, specimen containers, or data collection forms.

k. Prepare and distribute instructional materials regarding the study procedures and use these to conduct standardized training for study investigators and staff and clinical monitors using the Manual of Procedures and other materials.

l. Prepare and distribute instructional materials regarding the study laboratory procedures and specimen collection and preparation for shipping/transport.

m. Package, inventory, ship, and track specimens to the appropriate site as directed by Project Officer. Prepare standard operating procedures for notification of shipment and verification of shipment receipt, to include condition of specimens on arrival.

n. At the Project Officers request assist in tracking the revisions to the draft clinical trial agreements (CTA) or Cooperative Research and Development Agreements (CRADA) for each study involving an industrial sponsor(s) for that study. The draft CTAs or CRADAs shall address the cost to the Coordinating and Biostatistics Center associated with data management and site monitoring, as appropriate, as well as clinical site costs. A signed CTA or CRADA shall be in place prior to the initiation of each study.

o. Prepare abstracts/protocol summaries for NIH clinical trials database, DMID and NIAID databases and other databases as specified by the Project Officer, and serve as a call-in center for the public regarding information on FWD RNU studies summarized in the NIH Clinical Trials Database and on the NIAID website.

p. Develop and maintain a tracking system (including expected timelines) in conjunction with the Research Units for implementation and completion of the studies including study accrual for clinical studies , data analysis, manuscript and completion.

5. Regulatory:

a. Assist in assuring that all FWD IRN CRUs are in compliance with all Federal regulations and NIH policies applying to the conduct of research involving human subjects including, but not limited to, Title 21 CFR 11, 50, 56 and 312, and Title 45 CFR 46.

b. Provide support for requirements associated with Investigational New Drug (IND) applications for clinical trials of experimental therapies including, but not limited to:

1) providing technical and administrative assistance in the preparation and assembly of original and subsequent IND submissions including interim and annual reports. Includes review of consents for consistency for multi-center trials;
2) tracking of responses to specific inquiries from FDA officials related to clinical protocol design and IND submissions;
3) maintaining back-up files on all IND correspondence and submissions to the FDA for FWD IRN CRU sponsored clinical trials;
4) compiling final study report and manuscripts;
5) in the event of an international trial coordinate international clearances and other documents as required.

c. Enter and keep current FWD IRN studies in DMID's database e.g., HSROAD. At the direction of the Project Officer, develop ancillary systems as needed to maintain a computerized clinical site registration system including but not limited to:

1) assembling and tracking initial and subsequent modifications of registration documentation submitted by clinical sites participating in clinical trials including copies of the FDA Form 1572, Curricula Vitae, conflict of interest disclosure, IRB approval for each protocol, protocol amendment, consent form, and, study advertisements;
2) assuring adherence to the informed consent forms submitted by each site to the NIAID-approved informed consent template for each study;
3) confirming satisfactory completion of all procedures necessary for site registration to DMID Office of Regulatory Affairs (ORA) and the Project Officer and notifying clinical sites that registration has been completed for a particular protocol to allow initiation of study product shipment and enrollment of study participants;
4) providing site registration status reports to the NIAID, the CRUs, protocol team, and Executive Committees;
5) confirming Office of Human Research Protections (OHRP) project assurance for each Research Unit site engaged in human subjects research. No non-U.S., or U.S. site may participate in a FWD IRN study until documentation of compliance with these regulations has been submitted and prospectively approved by the Project Officer;
6) maintaining site-specific back-up regulatory files for each study.

d. Establish and maintain a system for the receipt, follow-up, tracking, and disposition in coordination with the DMID central database, of serious adverse experience (SAE) reports for all FWD IRN clinical trials. Some examples of SAEs include events resulting in:

1) death;
2) a life threatening experience;
3) inpatient hospitalization or prolongation of existing hospitalization;
4) congenital anomaly or birth defect;
5) persistent or significant disability or incapacity.
6) other important medical events that may not result in death, be life-threatening, or require hospitalization but may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the study participant and may require medical or surgical intervention to prevent one the outcomes listed above.

e. Satisfy FDA regulations and NIAID guidelines as related to processing of SAE reports and safety information by:

1) developing and distributing to participating clinical sites SAE reporting forms, standard operating procedures for processing adverse event data, and appropriate instructions or manuals. The forms shall be developed in coordination with CRU investigators and NIAID and shall conform to FDA regulations and NIAID guidelines;
2) establishing and maintaining a system for receiving faxes of SAE reports and related safety information 24 hours/day;
3) providing personnel during normal working hours to assemble and distribute this information to appropriate Coordinating and Biostatistics Center staff concerned with regulatory affairs (hereinafter referred to as the Regulatory Specialist or RS);
4) working with clinical site staff RN, the RS will obtain follow-up information, and/or reconcile discrepancies between SAE data reported versus SAE data collected on study forms. The SAE will be assessed by the RN and relevant information for each SAE will be summarized, when appropriate, for submission to the NIAID, study chairs, and industrial sponsors, if any;
5) abstracting and entering SAE data into the Coordinating and Biostatistics Center database within 72 hours of receipt.
6) Preparing draft safety reports for submission to the NIAID following the established FDA regulations and NIAID guidelines.
7) Distributing final versions of SAE and safety reports to industrial sponsors (if any) any to study investigators and track submission to their Institutional Review Boards (IRB). The RS shall transmit SAE reports as designated by the Office of Regulatory Affairs (ORA) and the Office of Clinical Research Affairs (OCRA), DMID, NIAID, to site investigators to share with their respective IRB's.
8) Developing, implementing, and maintaining quality control/assurance procedures and ongoing training of clinical site staff to ensure consistency, completeness, and accuracy of SAE reporting.
9) Generating line listings of all adverse events occurring in each specific FWD IRN clinical study for which NIAID is the IND sponsor for annual and final reports to the FDA and as requested by the Project Officer.

f. Distribute the investigator's brochure to the clinical sites when NIAID holds the IND for an investigational drug.

g. Attend and participate in a DMID regulatory workshops to discuss clinical trial coordination and regulatory issues related to clinical trials.

h. Track distribution of study drugs to participating clinical sites and, ultimately, the disposition of study drug by those clinical sites as instructed by the Project Officer. The Contractor shall develop a plan for tracking the distribution and ultimate disposition of study drugs, in collaboration with the Project Officer, for selected trials where this function is needed. The Contractor may be requested to store study drug.

6. Clinical Site Monitoring:

a. Monitor Study Group clinical sites participating in FWD IRN studies to ensure completeness and accuracy of study data and adherence with good clinical practice standards, protocol specifications, regulatory requirements, and other relevant Federal policies where NIAID holds the IND, unless otherwise instructed. The Contractor shall be responsible for assuring that the monitors have sufficient clinical background and be trained to effectively perform the required tasks. The Contractor shall provide the monitors with protocol-specific orientation and assignments by the clinical trial specialists, data managers, the protocol chairs and/or other protocol team members, as appropriate, and NIAID.

b. Provide a thorough review to site personnel of Federal regulations governing informed consent, Institutional Review Boards, responsibilities of sponsors and investigators, and protection of human subjects from research risks. A thorough explanation of NIAID policies and procedures, good clinical research practices, as appropriate, will also be provided.

c. Conduct interim site monitoring visits to participating Study Group clinical sites to evaluate selected data elements, as designated by senior statistical staff with input from the study teams, to include verification of adherence to study requirements and procedures, for a subset of patients (usually a 10% sample and possibly a higher percentage when specified by the Project Officer). In conducting annual (or more often, as necessary) interim site monitoring visits, the Contractor shall:

1) Assess the operation and management of the CRUs, including but not limited to:

a) site management.
b) organization and utilization of site staff;
c) communication among clinical, technical and administrative staff;
d) regulatory files;
e) adequacy of site facilities, pharmacy and study equipment including security measures in place to ensure patient confidentiality and standardization of methodologies.

2) Assess site compliance with the requirements for the CRU protocols being conducted, including but not limited to:

a) Compliance with the manual of operations.
b) Adherence to inclusion and exclusion criteria.
c) Reporting of SAEs.
d) Appropriate collection, storage and transport of patient samples.
e) Accuracy, timeliness and completeness of data collection and entry.
f) Accuracy of the data by source document verification.
g) Documentation of study endpoints.
h) Clinical records maintenance.
i) Study product accountability.
j) Challenge facilities and SOPs

d. Provide more thorough monitoring of CRU sites that have significant deficiencies discovered until those deficiencies are corrected as determined by the Project Officer.

e. Submit reports on CRU site performance after each monitoring visit. Summaries of the findings for each site shall be provided to the Project Officer and the appropriate CRU coordinator within two weeks of the site visit. In addition, if major concerns regarding site performance are noted, the monitor shall notify the Project Officer by telephone as soon as possible. The reports shall identify any site-specific operational issues or problems. In consultation with the CRU PI and NIAID, the Contractor shall formulate actions to be taken to address them and track them until they are resolved.

f. Receive and participate in review of site monitoring reports prepared for studies where the industrial sponsor is conducting site monitoring. The Contractor shall also perform site visits to other DMID or FWD IRN sites under industry sponsorship when directed by the Project Officer.

7. Data Analyses and Reporting

a. Design and conduct interim and final statistical analyses of study data as directed by the Project Officer and in collaboration with FWD IRN investigators, NIAID staff, agency representatives (if any), and industry sponsors (if any) including but not be limited to:

b. Conduct comprehensive statistical analyses, including relevant subgroup and exploratory analyses.

c. Prepare interim analyses data on the safety, toxicity, and efficacy of interventions evaluated in studies for presentation to and review by the DSMBs, SMCs, and the NIAID that shall also include analyses of data on accrual, retention, loss to follow-up and other status indicators relevant to the conduct of the studies.

d. Respond to requests for additional analyses from the FWD IRN investigators, DSMBs, SMCs, and NIAID.

e. Prepare study status and site-specific performance reports including, but not limited to, accrual and retention of study participants, timeliness of data submission, and adherence to protocol specifications at least quarterly for Executive Committee for review, the appropriate DSMB or SMC, and the NIAID with recommendations for improvements and modifications to resolve such study issues and problems.

f. Prepare reports based on the interim analyses data on the safety, toxicity, and efficacy of interventions evaluated in studies for presentation to and review by the DSMBs, SMCs, and the NIAID.

g. Participate in the preparation of scientific manuscripts and reports of the studies for publication in the peer-reviewed literature and presentation of the study results at relevant scientific meetings in collaboration with the protocol chairs, other FWD IRN investigators, NIAID staff, and others, as appropriate. (See Appendix I for guidelines.)

8. Transition

a. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract expiration a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies and for general Operating Center operating procedures. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management systems as well as on particular study records and data sets.

b. Upon completion of this contract, all data and specimens (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

**[END OF STATEMENT OF WORK]**

## Notes To Offerors

Food & Waterborne Diseases Integrated Research Network: Coordinating and Biostatistics Center
**DMID-03-28**

NOTE (1): The expertise of staff and organizational experience are critical elements. Include an organizational structure and management plan to include the responsibilities of staff and duties under contract. The offeror shall have expertise including but not limited to Biostatistics, Data Management and knowledge of all Federal Regulations and NIH policies applying to the conduct of research involving human subjects including, but not limited to, Title 21 CFR 11, 50, 56, and 312, and Title 45 CFR 46.

NOTE (2): The CoBC will provide administrative, biostatistical and technical support for the research units or other DMID groups as directed by the Project Officer. The offeror must submit a plan that details how it will coordinate the activities of the Units including mechanisms to integrate and complement the scientific agendas of each Unit and specifically the activities detailed in the Statement of work.

NOTE (3): The Offeror's role in the support of each study will be defined by the Project Officer. Offerors must have the flexibility to adjust the relative time commitments of their staff to meet the varying needs of the studies to be undertaken.

NOTE (4): For purposes of budgeting, the Offeror should assume that approximately twelve (12) clinical studies (i.e., studies conducted in the CRUs) will be initiated during this contract period, approximately two thirds of these studies will be Phase I and one third Phase II clinical trials.

NOTE (5): The Offeror should budget for at least three staff members, to include the PI or designee, to attend the start-up and annual scientific meetings of the FWD IRN in Bethesda, Maryland. These meetings will typically last two and one half days.

NOTE (6): The Offeror must submit standard operating procedures for quality control as part of their proposal. ((SOW, Paragraph 3. Data Management and Systems Development)

NOTE (7): The Offeror must describe in detail the various components of the proposed systems and how they will function with respect to each Research Unit activities; also, predicted upper limits for time duration of the steps needed to accomplish the data management procedures described above must be provided. (SOW, Paragraph 3)

NOTE (8): The FWD IRN Executive membership will include the PI of each of the Research Units, the PI of the Coordinating and Biostatistics Center and the NIAID Project Officer. The Executive Committee will meet on a monthly basis by telephone and at least once annually in the Bethesda, Maryland area. Ad-Hoc consultants up to seven (7) members will be appointed by the NIAID to provide input on priorities for food and waterborne diseases research, review the plans for upcoming FWD IRN studies and the overall progress of the FWD IRN. Typically, the Consultants will meet annually in the Bethesda, Maryland area. (SOW, Paragraph 4b)

NOTE (9): The Offeror must include a model protocol template as an example with the proposal. (SOW, Paragraph 4c)

NOTE (10): The Offeror must propose a budget that includes all costs associated with conference calls and travel expenses to attend meetings related to protocol development and implementation. (SOW, Paragraph 4e)

NOTE (11): The Investigational New Drug (IND) sponsor for FWD IRN clinical trials may be the NIAID or an industrial sponsor. In instances where the industrial sponsor serves as the IND sponsor, the Offeror will <u>not</u> be responsible for carrying out the regulatory functions described in this section. In instances where NIAID holds the IND, the Offeror will assist and interact with the Office of Clinical Research Affairs (OCRA) and the Office of Regulatory Affairs (ORA), DMID in carrying out these regulatory functions. It is anticipated that the NIAID will hold the INDs for almost all new studies.(SOW, Paragraph 5b)

NOTE (12): The Offeror must provide a proposed SOP for receipt, follow-up, tracking, and disposition of SAE reports. (SOW, Paragraph 5d)

NOTE (13): The individuals serving as clinical trial and regulatory specialists should attend these 2-day meetings to be held in Bethesda, Maryland each year. (SOW, Paragraph 5g)

NOTE (14): For purposes of budget construction, the Offeror should assume that each trial minimally will require an initial visit, interim visits, and close out. Interim visits will depend on the size and complexity of the study. (SOW, Paragraph 6)

NOTE (15): Offerors should check the links below for Guidance for activities involving human subjects:

Office for Human Research Protections, http://ohrp.osophs.dhhs.gov/

Monitoring of clinical trials and studies policy, http://grants.nih.gov/grants/guide/notice-files/NOT-AI-00-003.html

NIH policy on reporting race and ethnicity data: subjects in clinical research, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html

Title 45--Public Welfare, Subtitle A –Department of Health and Human Services, Part 46—Protection of Human Subjects, http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html

It is NIH policy that children (i.e., individuals under the age of 21) must be included in all human subjects research conducted or support by NIH, unless there are scientific or ethical reasons not to include them. http://grants.nih.gov/grants/funding/children/children.htm

OER implementation of inclusion of children, http://odoerdb2.od.nih.gov/oer/policies/children.htm

*NIH Guide* notice on inclusion of children in studies, http://grants.nih.gov/grants/guide/notice-files/not98-024.html

All applicants participating in clinical research must document that they have completed training in the protection of human research participants by sending us a letter stating they have done so.

PHS Policy on Instruction in the Responsible Conduct of Research (RCR), http://ori.dhhs.gov/html/programs/finalpolicy.asp

*NIH Guide* notice, September 5, 2001, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html

*NIH Guide* notice, December 5, 2000, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-007.html

NIAID *Council News* article, December 21, 2000, http://www.niaid.nih.gov/ncn/newsletters/nl122100/nl122100.htm#6

NIAID *Council News* article, October 12, 2000, http://www.niaid.nih.gov/ncn/newsletters/nl101200/nl101200.htm#1

OER research training site, http://grants.nih.gov/training/index.htm

Sample letter to document research training, http://www.niaid.nih.gov/ncn/newsletters/nl090700/sample.htm

OHSR computer based training for researchers, Protection of Human Subjects, http://ohsr.od.nih.gov/cbt/

Document library, Office for Human Research Protections, http://ohrp.osophs.dhhs.gov/polasur.htm

NIAID Council News roadmap for human subjects policies, http://www.niaid.nih.gov/ncn/tools/humansubjects/default.htm

Human subject regulations decision charts,
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm
http://ohrp.osophs.dhhs.gov/irbasur.htm

Policy and Guidelines for Data and Safety Monitoring are available on the NIAID website (http://www.niaid.nih.gov/dmid/clinresearch/ ). The SMCs meet by teleconference call at least once during the study accrual period and are composed of approximately three (3) members consisting of a study investigator, the NIAID Medical Officer, and an investigator independent of the Study Group and the study. The DSMBs will be composed of approximately five (5) members each and will be appointed by the NIAID. The DSMBs will meet at least annually in the Bethesda, Maryland and will typically convene by teleconference call once between these meetings.

**Reporting Requirements**
**Food & Waterborne Diseases Integrated Res. Net.: Coordinating & Biostatistics Ctr.**
**RFP DMID-03-28**

## DELIVERABLES AND REPORTING REQUIREMENTS

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports shall be brief and factual and prepared in accordance with the format specified below.

A. Accrual And Site Registration Report

At specified time points to be determined by the Protocol Team and approved by the Project Officer, the Contractor shall submit a report for each open clinical protocol sponsored by the FWD IRN summarizing:

1. For each clinical site enrolling study participants in open clinical protocols: projected overall accrual at each site; date of first enrollment; actual accrual to date; summary of all eligible patients per month and to date; and, reasons for non-entry of eligible patients.
2. For each clinical site in the process of registering and obtaining approval to participate in open clinical protocols: outstanding requirements for approval; anticipated date of approval; projected accrual; and, any anticipated problems with protocol approval/implementation.
3. Summary of the projected versus actual accrual to date for all approved clinical sites, and reasons for non-entry of eligible patients.
4. Recommendations for modifications in study design, clinical site monitoring, or clinical site training appropriate to improve overall or site-specific accrual, including recommendations for increasing the number of participating clinical sites.

Three copies of the Accrual and Site Registration Reports shall be provided to the NIAID Project Officer; additionally, one copy of the report shall be provided to the Principal Investigators of the FWD IRN CRUs.

B. Report on CRU Site Performance After Monitoring Visit

Submit reports on CRU Site Performance after each monitoring visit. Summaries of the findings for each site shall be provided to the Project Officer and the appropriate CRU coordinator within two weeks of the site visit. In addition, if major concerns regarding site performance are noted, the monitor shall notify the Project Officer by telephone as soon as possible. The reports shall identify any site-specific operational issues or problems.

Three copies of the CRU Site Performance Reports shall be provided to the NIAID Project Officer; additionally, one copy of the report shall be provided to the Principal Investigators of the FWD IRN CRUs.

C. Monthly Adverse Event Report

The Contractor shall submit a report on all adverse experiences for each CRU open clinical protocol, including copies of adverse experience report forms. One copy shall be provided to the NIAID Project Officer and one copy shall be provided to the IRN Executive Committee.

D. Quarterly Technical Progress Report

The Contractor shall submit a report summarizing the activities undertaken during the reporting period, as follows:

*1. Status of Protocol Development*

a. Pending protocols for proposed clinical trials, including: lead investigator(s); stage of development; step within the NIAID review process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and, time frame for completion of review, approval, modification or disapproval.

b. A summary of issues or problems encountered with respect to the NIAID and/or the Protocol Team review and decision-making process, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of the review processes.

2. *Status of FWD IRN Research Unit Projects and Project Proposals*

a. Pending projects, including: lead investigator(s); stage of development; step within the NIAID review process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and, time frame for completion of review, approval, modification or disapproval.

b. A summary of issues or problems encountered with respect to the NIAID and/or the FWD IRN review and decision-making process, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of the review processes.

c. A table charting the progress of FWD IRN approved projects including progress on milestones.

Three (3) copies of the Quarterly Technical Progress Report shall be provided to the NIAID Project Officer; additionally, one (1) copy shall be provided to the Principal Investigators of each of the FWD IRN Research Units and one copy to the Contracting Officer.

E. Semiannual Technical Progress Report

Semiannually and at the completion of each Project, the Contractor shall submit a summation of the work performed and the results obtained. This report shall be prepared by the Principal Investigator of the FWD IRN with the administrative and biostatistical support of the CoBC. The report should be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved, and shall summarize data analyses performed in text, tabular and graphical form. This report shall include, but not be limited to, a summary of all relevant descriptive information for all research units, and for the clinical studies include accrual data, attrition, number of forms received, number of data edits, clinical site monitoring reports, adverse events, and safety information. In addition, this report shall include budget information including spent this period (six months), spent to date, balanced, and proposed spending for the next six-month period.

Each semi-annual report shall be due on or before 30 days following the end of each 6-month period beginning with the start of the contract. Three (3) copies of all reports shall be provided to the NIAID Project Officer and one (1) copy to the Contracting Officer.

F. Annual Technical Progress Report

On an annual basis, the Contractor shall submit a report summarizing the results of the entire contract work for the period covered, with separate reports prepared for each Project and/or Protocol for the components as specified below. These Annual Reports shall be in sufficient detail to explain comprehensively the status of these activities and results achieved, if applicable. Annual Reports shall be submitted thirty (30) days after the anniversary date. Three (3) copies of these reports shall be provided to the Project Officer and one (1) copy to the Contracting Officer.

1. *Statistical Design Considerations*
   a. The advantages and disadvantages of the various approaches to the statistical design of ongoing and completed FWD IRN clinical trials for the assessment of the safety, toxicity and efficacy of treatments under study, including: control and comparison groups, inclusion and exclusion criteria, sample size; research questions addressed; clinical endpoints, number and type of patient samples, etc.
   b. Recommendations for improved statistical approaches and methods to improve criteria for evaluating the diseases being studied.

2. *Standard Operating Procedures*, including:
   a. Development, review and implementation of approved projects, including criteria for evaluation and prioritization.
   b. Clinical site monitoring and training with respect to adherence to protocol requirements, data collection and quality assurance, and adherence to regulatory requirements.

c. Preparation, review and approval of requests for statistical analyses.
d. Review and approval of publications, abstracts, reports and presentations.
e. Monitoring and evaluating the performance of clinical study sites and procedures for addressing performance problems.

3. *Clinical Site Monitoring And Training*, including:
   a. Clinical site training activities conducted, including written materials on CRU standard operating procedures and protocol-specific requirements;
   b. Issues and problems encountered in the training and monitoring of CRUs.
   c. Recommendations for modifications/improvements in training materials and/or standard operating procedures to ensure adherence to protocol requirements, standard operating procedures and regulatory requirements.

4. *Regulatory Functions and Requirements*, including:
   a. Compilation of information for IND annual reports in response to DMID regulatory requests.
   b. Issues and problems in the coordination and assembly of IND documents when DMID is the IND holder.
   c. Recommendations for improvements/modifications in FWD IRN CoBC regulatory procedures.
   d. Provide final study reports for submission to the FDA.

5. *Monitoring Progress And Evaluating Performance*, including:
   a. Assessment of policies and procedures used by the FWD IRN.
   b. Recommendations for improvements.

G. Final Report And Deliverables

At the completion of the contract, the Contractor shall deliver to the Contracting Officer a cleaned, edited, documented public use data set containing all study data, on media to be determined at the time of delivery, as specified by the Project Officer, and copies of all data management tools, including, but not limited to, data documentation and data dictionaries, data entry software and editing programs to allow reading and analysis of the data. The Contractor shall provide to the Government appropriate computer programs capable of: (1) reading and manipulating all data, and (2) creating SAS compatible databases. Additionally, at the completion of the contract, the Contractor shall deliver to the Project Officer an audit trail of all raw data corrections, hard copies of the original data collected from study participants from all studies supported by this contract, and all logs, other records, and source codes related to data collection, entry, editing, analysis and transfer.

H. Other Deliverables

1. Prepare a plan for activation of the Food and Waterborne Diseases Integrated Research network at the direction of the Project Officer in response to a bioterrorist event. Submit within first 6 months of the award date. This will be one of the first tasks of the FWD IRN Executive Committee. This plan must include contact information and a mechanism for rapidly connecting all persons named on the Emergency Response Team.

2. Provide the Project Officer and/or FWD IRN Research Unit investigators with information or reports as requested regarding any project. Such information may include, but not be limited to:

   a. Preparation of reports, analyses and recommendations for the Executive Committee and assistance in implementing necessary modifications approved by this body, including revised clinical protocols or Research Unit Projects.

   b. Preparation of materials such as tables, text, graphs, and diagrams as needed in collaboration with investigators and NIAID staff for presentation at study meetings or professional meetings and other special reports concerning study findings.

   c. Preparation of reports with custom formats and selection groups summarizing data for monitoring study progress or product safety or for use by separate site monitoring Contractor, if requested.

   d. Preparation of abstracts/protocol summaries for NIH clinical trials database and other databases specified by the Project Officer.

3. Design and conduct interim and final statistical analyses of study data as defined in the protocol. Prepare reports as directed by the Project Officer in collaboration with the NIAID Data Safety Monitoring Boards, Safety Monitoring Committees, or Safety Monitor. The reporting frequency and distribution of reports should be consistent with the requirements specified by the Safety Monitor, Safety Monitoring Committee or Data Safety Monitoring Board for each FWD IRN clinical protocol. The reports should include: interim analyses of data on the safety, toxicity, and efficacy of interventions and shall also include analyses of data on accrual, retention, loss to follow-up and other status indicators relevant to the conduct of the studies. Respond to requests for additional analyses from the FWD IRN investigators, Safety Monitor, Safety Monitoring Committee, Data Safety Monitoring Board and NIAID.

4. Prepare study status and site-specific performance reports including, but not limited to, accrual and retention of study participants, timeliness of data submission, and adherence to protocol specifications at least quarterly for Executive Committee for review, the appropriate Data Safety Monitoring Board or Safety Monitoring Committee, and the NIAID with recommendations for improvements and modifications to resolve such study issues and problems.

5. Participate in the preparation of scientific manuscripts and reports of the studies for publication in the peer-reviewed literature and presentation of the study results at relevant scientific meetings in collaboration with the protocol chairs, other FWD IRN investigators, NIAID staff, and others, as appropriate.

6. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract expiration a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies and for general Operating Center operating procedures. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management systems as well as on particular study records and data sets.

7. Upon completion of this contract, all data and specimens (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

I. TECHNICAL REPORT DISTRIBUTION:

| Item | Type of Deliverable | Description | Initial Report Due | Subsequent Reports Due |
|---|---|---|---|---|
| A. | Accrual And Site Registration Report | Outlined Above | TBD | TBD by Protocol Team and Project Officer |
| B. | Report on CRU Site Performance After Monitoring Visit | Outlined Above | TBD | Within two weeks after site visit |
| C. | Quarterly Technical Report | Outlined Above | TBD | Quarterly |
| D. | Semi Annual Technical Progress Report | Outlined Above | TBD | Semi Annually; due on or before 30 days following the end of each 6 month period, beginning with the start of the contract. |
| E. | Annual Technical Progress Report | Outlined Above | TBD | Annually; submitted 30 days after the anniversary date. |
| F. | Final Report and Deliverables | Outlined Above | | On or before the completion date of the project. |

J. ADDRESSEES:

| Item | Number of Copies | Recipient | Address |
|---|---|---|---|
| A, B, C, D, E | 3 | Project Officer | Project Officer<br>6700-B Rockledge, Room 3107<br>MSC 7630<br>Bethesda, MD 20892-7630 |
| A, B, C | 1 | Principal Investigators of FWD IRN CRU's | TBD |
| C, D, E, F | 1 | Contracting Officer | Contracting Officer<br>CMB, DEA, NIAID<br>6700-B Rockledge, Room 2106 MSC 7612<br>Bethesda, MD 20892-7612 |

## PART I - THE SCHEDULE

## SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

**A Sample Uniform Contract Format may be found at the following website:**

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

**[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]**

## PART II – CONTRACT CLAUSES

## SECTION I - CONTRACT CLAUSES

**THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.**

**BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.**

**ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

| FAR Clause No. | Date | Title |
|---|---|---|
| 52.202-1 | Dec 2001 | Definitions |
| 52.203-3 | Apr 1984 | Gratuities (Over $100,000) |
| 52.203-5 | Apr 1984 | Covenant Against Contingent Fees (Over $100,000) |
| 52.203-6 | Jul 1995 | Covenant Against Contingent Fees (Over $100,000) |
| 52.203-7 | Jul 1995 | Anti-Kickback Procedures (Over $100,000) |
| 52.203-8 | Jan 1997 | Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000) |
| 52.203-10 | Jan 1997 | Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000) |
| 52.203-12 | Jun 1997 | Limitation on Payments to Influence Certain Federal Transactions (Over $100,000) |
| 52.204-4 | Aug 2000 | Printing/Copying Double-Sided on Recycled Paper (Over $100,000) |
| 52.209-6 | Jul 1995 | Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000) |
| 52.215-2 | Jun 1999 | Audit and Records - Negotiation (Over $100,000) |
| 52.215-8 | Oct 1997 | Order of Precedence – Uniform Contract Format |
| 52.215-10 | Oct 1997 | Price Reduction for Defective Cost or Pricing Data |
| 52.215-12 | Oct 1997 | Subcontractor Cost or Pricing Data (Over $500,000) |
| 52.215-14 | Oct 1997 | Integrity of Unit Prices (Over $100,000) |
| 52.215-15 | Dec 1998 | Pension Adjustments and Asset Reversions |
| 52.215-18 | Oct 1997 | Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions |
| 52.215-19 | Oct 1997 | Notification of Ownership Changes |
| 52.215-21 | Oct 1997 | Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications |
| 52.216-7 | Feb 2002 | Allowable Cost and Payment |
| 52.216-8 | Mar 1997 | Fixed Fee |
| 52.219-6 | Jul 1996 | Notice of Total Small Business Set-Aside |

| | | |
|---|---|---|
| 52.219-8 | Oct 2000 | Utilization of Small Business Concerns (Over $100,000) |
| 52.219-9 | Jan 2002 | Small Business Subcontracting Plan (Over $500,000) |
| 52.219-16 | Jan 1999 | Liquidated Damages - Subcontracting Plan (Over $500,000) |
| 52.222-2 | Jul 1990 | Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.) |
| 52.222-3 | Aug 1996 | Convict Labor |
| 52.222-26 | Apr 2002 | Equal Opportunity |
| 52.222-35 | Dec 2001 | Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans |
| 52.222-36 | Jun 1998 | Affirmative Action for Workers with Disabilities |
| 52.222-37 | Dec 2001 | Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans |
| 52.223-6 | May 2001 | Drug-Free Workplace |
| 52.223-14 | Oct 2000 | Toxic Chemical Release Reporting |
| 52.225-1 | May 2002 | Buy American Act - Supplies |
| 52.225-13 | Jul 2000 | Restrictions on Certain Foreign Purchases |
| 52.227-1 | Jul 1995 | Authorization and Consent, Alternate I (Apr 1984) |
| 52.227-2 | Aug 1996 | Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000) |
| 52.227-11 | Jun 1997 | Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual. |
| 52.227-14 | Jun 1987 | Rights in Data – General |
| 52.227-14 | Jun 1987 | Rights in Data - General, Alternate IV (Jun 1987) |
| 52-232-9 | Apr 1984 | Limitation on Withholding of Payments |
| 52.232-17 | Jun 1996 | Interest (Over $100,000) |
| 52.232-20 | Apr 1984 | Limitation of Cost |
| 52.232-23 | Jan 1986 | Assignment of Claims |
| 52.232-25 | Feb 2002 | Prompt Payment |
| 52.232-34 | May 1999 | Payment by Electronic Funds Transfer--Other Than Central Contractor Registration |
| 52.233-1 | Dec 1998 | Disputes |
| 52.233-3 | Aug 1996 | Protest After Award |
| 52.242-1 | Apr 1984 | Notice of Intent to Disallow Costs |

| | | |
|---|---|---|
| 52.242-3 | May 2001 | Penalties for Unallowable Costs (Over $500,000) |
| 52.242-4 | Jan 1997 | Certification of Final Indirect Costs |
| 52.242-13 | Jul 1995 | Bankruptcy (Over $100,000) |
| 52.243-2 | Aug 1987 | Changes - Cost Reimbursement, Alternate V (Apr 1984) |
| 52.244-2 | Aug 1998 | Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings. |
| 52.244-5 | Dec 1996 | Competition in Subcontracting (Over $100,000) |
| 52.245-5 | Jan 1986 | Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract) |
| 52.246-23 | Feb 1997 | Limitation of Liability (Over $100,000) |
| 52.249-6 | Sep 1996 | Termination (Cost-Reimbursement) |
| 52.249-14 | Apr 1984 | Excusable Delays |

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

| HHSAR Clause No. | Date | Title |
|---|---|---|
| 352.202-1 | Jan 2001 | Definitions - with Alternate paragraph (h) (Jan 2001) |
| 352.228-7 | Dec 1991 | Insurance - Liability to Third Persons |
| 352.232-9 | Apr 1984 | Withholding of Contract Payments |
| 352.233-70 | Apr 1984 | Litigation and Claims |
| 352.242-71 | Apr 1984 | Final Decisions on Audit Findings |
| 352.270-5 | Apr 1984 | Key Personnel |
| 352.270-6 | Jul 1991 | Publication and Publicity |

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 05/2002]

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

## SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

**PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)**

**HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)**

**PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: October 25, 2002] (Attached to this listing)**

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

**RFP FORMS AND ATTACHMENTS:**

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

**APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):**

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

**APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):**

- **NIH-2043, Proposal Summary and Data Record**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

**TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):**

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Privacy Act System of Records**
- **Report of Government Owned, Contractor Held Property**
- **Disclosure of Lobbying Activities, OMB Form LLL**

**PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL**

*Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.*

*PAPER SUBMISSION:* The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

*ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.*

*SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.*

## Shipment and marking of paper copies shall be as indicated below:

**A. EXTERNAL PACKAGE MARKING:**

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DMID-03-28
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

**B. NUMBER OF COPIES:**

The number of copies required of each part of your proposal are as specified below.

**Technical Proposal:** One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

**Business Proposal:** One (1) unbound signed original and 5 unbound copies.

**C. PAPER COPIES and CD-Rom or ZipDisk to:**

| If Hand Delivery or Express Service | If using U.S. Postal Service |
|---|---|
| Lisa K. Coleman<br>Contract Specialist<br>Contract Management Branch, DEA<br>NIAID, NIH<br>6700-B Rockledge Drive, Room 2230<br>Bethesda, Maryland 20817 | Lisa K. Coleman<br>Contract Specialist<br>Contract Management Branch, DEA<br>NIAID, NIH<br>6700-B Rockledge Drive, Room 2230, MSC 7612<br>Bethesda, Maryland 20892-7612 |

*NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.*

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

# HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

**PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED __75__ PAGES**
[INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

**Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.**

**ELECTRONIC SUBMISSION** – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

**Formatting Requirements:**

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

**SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":**

**Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions.** For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

**CREATE ADOBE PDF ONLINE** -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

**LOG-IN / TRANSMISSION INSTRUCTIONS:**

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided by the Contract Specialist.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

**USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).**

# PROPOSAL INTENT RESPONSE SHEET

**RFP No.:** NIH-NIAID-DMID-03-28
**RFP Title:** Food & Waterborne Diseases Integrated Research Network: Coordinating and Biostatistics Center

Please review the attached Request for Proposal. Furnish the information requested below and return this page by October 25, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

**Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.**

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

**Company/Institution Name (print):** _____
**Address (print):** _____
_____
_____
_____

**Project Director's Name (print):** _____
**Title (print):** _____
**Signature/Date:** _____
**Telephone Number and E-mail Address (print clearly):**
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

**Name:** _____
**Title:** _____
**E-Mail Address:** _____
**Telephone Number:** _____

**Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):**

_____
_____
_____
_____
*(Continue list on a separate page if necessary)*

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Lisa K. Coleman
RFP-NIH-NIAID-DMID-03-28
FAX# (301) 480-5253
Email : lc304t@nih.gov

## PART IV – REPRESENTATIONS AND INSTRUCTIONS

# SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

### Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

**IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.**

# SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

**1.** GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

*Discussions* are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

*(1)* If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

*(2)* There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

*(3)* It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

**[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]**

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

**Alternate I** (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NOTICE OF SMALL BUSINESS SET-ASIDE**

(a) **General**. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

(b) **Definitions**. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

c. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710 .
(2) The small business size standard is 500 employees .

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that ONE AWARD(S) will be made from this solicitation and that the award(s) will be made on/about June 30, 2003.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost-reimbursement, completion type contract with a period of performance of approximately seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 15,261 total labor hours per year (7.3 FTEs/year). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

k. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

l. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

a. **GENERAL INSTRUCTIONS**

**INTRODUCTION**

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources

information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

**Hard Metric** - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

**Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

**Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Human Subjects**

**IMPORTANT NOTE TO OFFERORS: These paragraphs [(9) and (10)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."**

**This research project involves obtaining human subject specimens from Phase I/II clinical trials. The offeror(s) are responsible for assuring that the acquisition and supply of human specimen materials were obtained in accordance with NIH Policy. NIH Policy requires:**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

**Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)**

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, (telephone: 301-496-7014*), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR* an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/ Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.*

(10) **Instructions to Offerors Regarding Protection of Human Subjects**

*****(Note: The requirements in this paragraph (10), may be supplemented when necessary, based on the specific requirements of the solicitation.) *****

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

– Describe the proposed involvement of human subjects in response to the solicitation.

– Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

– Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

– Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

**Note:** If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

**Collaborating Site(s)**

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(11) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(12) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(13) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily and FedBizOpps.

(14) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(15) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(16) **Salary Rate Limitation in Fiscal Year 2002 ****

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

**Information regarding the FY-2002 rate can be found at: http://www.opm.gov/oca/02tables/ex.pdf**

It should be noted that a similar public law can be enacted in Fiscal Year 2003, that public law will be incorporated into any resultant contract.

(17) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

**INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS**

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(18) **Past Performance Information**

a) Offerors shall submit the following information as part of their BUSINESS proposal.

A list of the last five (5) contracts completed during the past three (3) years and the last three (3) contracts awarded currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract valued at over $500,000.

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(19) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(20) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

**OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.**

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(4) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

**General experience** is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

**Organizational experience** is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

**Performance history** is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

**Pertinent contracts** is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(5) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.

(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

**HHSAR 352.232-75, Incremental Funding (January 2001)**

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

**[ ]** The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

**[ ]** The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(6) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(7) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(8) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(9) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

# SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. **HUMAN SUBJECT EVALUATION**

This research project involves obtaining human subject specimens from Phase I/II clinical trials. The offeror(s) are responsible for assuring that the acquisition and supply of human specimen materials were obtained in accordance with NIH Policy. NIH Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NCI that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event

reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

## 3. PAST PERFORMANCE FACTOR

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal was determined to be unacceptable on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

Listed below are past performance subfactors to be used for evaluation purposes.

**Past Performance Subfactors**

- Record of conforming to specifications and to standards of good workmanship
- Record of forecasting and controlling costs under cost-reimbursement contracts
- Adherence to contract schedules, including the administrative aspects of performance
- Reputation for reasonable and cooperative behavior and commitment to customer satisfaction
- Business-like concern for the interest of the Customer

4. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

| **CRITERIA** | **WEIGHT** |
|---|---|
| **A. PERSONNEL** | **45 Points** |

Suitability of the staffing and management plans for the conduct of the project, including the appropriateness of the time commitments of all the proposed positions, the clarity and appropriateness of assigned roles, responsibilities, lines of authority (provide an organizational chart for all personnel and flow chart of the management of the project throughout the organization), and back-up staffing, and the evidence that they will be able to function as a team.

Documented experience of Principal Investigator in providing statistical advice and in managing and directing statistical and data management support, and any subcontractor or consultant that may be necessary for multi-center clinical trials.

Subcontractors: Documented training, experience and availability of any proposed Subcontractor (s), their documented capability to perform the proposed work, and expertise in similar projects. The logistical adequacy of the plan for the use of the Subcontractor (s) in the conduct of the project, including the time commitment of the professional and technical staff. Quality of the plan to identify the need to add, replace, or remove the Subcontractor's scientific staff, dependent on the progress or availability of new scientific information. Adequacy of plans for evaluating the performance of Subcontractor (s).

Documented expertise, appropriate training, experience, and availability of the statistical, clinical, regulatory, technical, and administrative staff, as well as subcontractors, required to plan and implement the requirements of this project as described in the Statement of Work.

This shall include the documented training, expertise, experience, leadership/management skills and availability of the Project Director and the surrounding leadership of the Coordinating and Biostatistics Center to successfully plan and manage the network. It is highly desirable that the advice and leadership be provided by senior, Ph.D. level staff with documented biostatistical and clinical trials expertise. Evidence of interactive collaboration with clinicians in the design, conduct, and analysis of clinical research studies is also highly desirable.

The team of professional personnel shall have documented composite expertise in Biostatistics, multicenter clinical trials, computer systems design and proficiency in statistical software, and data management, documented expertise in electronic connections to remote systems and proficiency with software and operating system (s) proposed to accomplish the Statement of Work. The Regulatory Specialist shall have an R.N. degree with sufficient clinical experience to perform the required duties. Administrative personnel must have demonstrated experience in management of research budgets and subcontract administration. All staff shall possess the requisite experience to perform their scientific and administrative duties. The Offeror must list credentials and experience for all personnel proposed, including support staff.

**B. TECHNICAL APPROACH** **35 Points**

Soundness and practicality of the technical approach for each of the requirements specified in the Statement of Work, with adequate explanation, substantiation, and justification for the recommended methods for handling the projected needs of the FWD IRN. Also, demonstration of the Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties which may arise in the performance of this work. This evaluation will assess:

a. Documented approach for establishing and operating a reliable, well-monitored, efficient and responsive study and data management system including the design and development of a reliable computer-based system for data management; implementation of procedures to handle data typically from multicenter clinical studies; and, interfacing with NIAID and study sites.

b. Documented approach for providing statistical leadership for the design, implementation, monitoring, modification, and analysis of clinical trials conducted by the Study Groups.

c. Documented approach for designing and implementing clinical site monitoring and training requirements.

d. Documented approach for the understanding of the scope and objectives of the contract, recognition of potential difficulties that may arise in performing the work required, and understanding of the close coordination necessary between the NIAID, the Executive Committee, the clinical sites and other study personnel, Data and Safety Monitoring Boards, Safety Monitoring Committees, and Ad Hoc Consultants and Advisors.

e. Documented approach for providing support for regulatory functions and requirements associated with Investigation New Drug (IND) Applications.

**C. ORGANIZATIONAL EXPERIENCE** **10 Points**

Adequacy of the administrative and organizational framework, with lines of authority and responsibility clearly demonstrated, and adequacy of the work plan, with proposed time schedule for achieving contract objectives and maintaining quality control over the implementation and operation of the project.

**D. FACILITIES AND RESOURCES** **10 Points**

Documented availability and adequacy of facilities, equipment and resources necessary to carry out all phases of this project.

**TOTAL = 100 Points**